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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,173	06/01/2001	Beth A. Burnside		2928

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EXAMINER
GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/872,173	Applicant(s) BURNSIDE ET AL.	
	Examiner Sharmila S. Gollamudi	Art Unit 1616	

-- Th MAILING DATE of this communication appears on the cov r sh t with th corr spond nce addr ss --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *1-11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-11 are included in the prosecution of this application.

Specification

A paragraph labeled 'Brief Description of Drawings' is required (Note MPEP 608.01 (f)).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 and 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faour et al (6,491,949).

Faour et al disclose a an osmotic device containing an drug core (7), a semi-permeable membrane surrounding core (6), a second drug layer (4), and a semi-permeable layer surrounding layer (3) (Note figure). The semi-permeable membrane is preferably made of a cellulose ester (cellulose acetate-butyrate) (col. 7, lines 23-27). The individual drug containing layers may contain from .10-99.9% of active (col. 9, lines 33-35). The active agents suitable are taught on column 13 to column 17.

Faour et al do not exemplify the recited greater concentration of the outer drug layer than the inner core.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to manipulate the conditions and general teachings of the prior art

to obtain the desired effect since Faour et al teach the active in each layer may be contained in a range of .10-99.9% and be individually varied. One would be motivated to do so depending on various parameters such as the identity and physical properties of the each drug employed, the dosage of drug employed, the desired effect of said drug, the intended application of osmotic device, and the physiological condition to be treated.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Faour et al (6,491,949) in view of Hamel et al (4,801,461).

The teachings of Faour et al have been set forth above. Faour et al teaches the use of decongestants and sympathomimetic drugs such as ephedrine (col. 14, lines 54-44).

Faour does not teach the use of pseudoephedrine.

Hamel teaches instant drug is a sympathomimetic amine and is used for relief of symptoms associated with the common cold (col. 1, lines 20-47).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate pseudoephedrine into Faour et al's device since Hamel teaches the use of instant drug to relieve cold symptoms. One would be motivated to do so with the expectation of similar results since Hamel teaches the instant drug is a sympathomimetic amine and Faour teaches the suitability of sympathomimetic drugs in the device.

Claims 1-3 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Savastano et al (5,681,584) in view of Fassihi et al (5,783,212).

Savastano et al teach a controlled release drug delivery device. The device contains a drug core, a delay jacket, a semi-permeable membrane, an additional drug layer that is placed between the delay jacket and semi-permeable membrane (Note claim 20). The active agents that are taught to be suitable are various proteins and peptides (col. 6, lines 33-65). The semi-permeable membrane is made of cellulose acetate (example 4).

Savastano does not specify the concentration of the actives in the respective layers.

Fassihi et al teach a controlled release device wherein the device contains three layers. The device contains at least one active layer with two barrier layers (abstract). The reference teaches optionally adding a pharmaceutical agent in one or more of the barrier layers. Fassihi teaches that this optional approach is beneficial when a high concentration of a drug is needed to be administered quickly to alleviate symptoms followed by low levels of a drug released to maintain an acceptable pharmaceutical level in the patient (col. 4, lines 13-25).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Savastano and Fassihi since Fassihi teaches the motivation of having a higher concentration of a drug in an outer layer compared to the inner drug layer. One would be motivated to do so since Fassihi teaches this allows for the device to quickly alleviate symptoms that require immediate action followed by maintaining the active in the blood with the release of the inner layer drug.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Savastano et al (5,681,584) in view of Faour et al (6,004,582).

Savastano et al teach a controlled release drug delivery device. The device contains a drug core, a delay jacket, a semi-permeable membrane, an additional drug layer that is placed between the delay jacket and semi-permeable membrane (Note claim 20). The active agents that are taught to be suitable are various proteins and peptides (col. 6, lines 33-65). The semi-permeable membrane is made of cellulose acetate (example 4).

Savastano does not specify the concentration of the actives in the respective layers. The reference does not teach recited drug in claim 6.

Faour et al teach a multi-layered osmotic device wherein the device contains a drug core and external drug layer. Faour teaches the core drug may vary in amount of .1-99.9% according to the particular active used and the intended use of the device (col. 9, lines 28-36). The external coat drug contains from .1-99% varying according to the characteristics and properties of the particular drug, does, desired effect, and intended use of device (col. 6, lines 42-54). Lastly, Faour teaches pseudoephedrine (examples).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Savastano et al and Faour et al since both teach controlled release device and Faour teaches manipulating the amount of active contained in the device to obtain the desired effect. One would be motivated to do so depending on various parameters such as the identity and physical properties of the each drug employed, the dosage of drug employed, the desired effect of said drug,

the intended application of osmotic device, and the physiological condition to be treated as taught by Faour et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 703-305-2147.. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 709-3080196.

SSG
December 23, 2002

JOSE G. DEES
SUPERVISORY PATENT EXAMINER
1616